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**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

ASTRAZENECA AB, AKTIEBOLAGET
HÄSSLE, ASTRAZENECA LP, KBI INC.,
and KBI-E INC.,

Plaintiffs and
Counterclaim Defendants,

V.

HANMI USA, INC., HANMI
PHARMACEUTICAL CO., LTD., HANMI
FINE CHEMICAL CO., LTD, and HANMI
HOLDINGS CO., LTD.,

Defendants and Counterclaim Plaintiffs.

Civil Action No. 3:11-CV-00760-JAP-TJB

DECLARATION OF JERRY L. ATWOOD, Ph.D.

I, Jerry L. Atwood, state and declare as follows:

Background

1. I reside at 5704 Short Line Dr., Columbia, Missouri 65203. I hold a B.S. degree in Chemistry and Mathematics from Southwest Missouri State University (1964) and a Ph.D. in Chemistry from the University of Illinois (1968).

2. I am Chairman of the Department of Chemistry at the University of Missouri-Columbia. In 1999, I became Curators' Professor at the University of Missouri-Columbia. I have been Chairman since 1994, when I came to the University as Professor. Before that, I was employed by the University of Alabama, where I successively held the titles of Assistant Professor, Associate Professor, Professor, and University Research Professor.

3. I have been Co-Editor-in-Chief of the *New Journal of Chemistry* since 2005. From 1985 to 1998, I was Editor of the *Journal of Chemical Crystallography*. In 1999, I was named Consulting Editor for the *Journal of Chemical Crystallography*. I was Associate Editor of *Chemical Communications* from 1996 to 2005. From 1992 until 2000, I was Editor of *Supramolecular Chemistry*. From 1985 to 1993, I was Regional Editor for the *Journal of Coordination Chemistry*. I am co-Editor of the Inclusion Compounds book series (five volumes), Comprehensive Supramolecular Chemistry (ten volumes), and the Encyclopedia of Supramolecular Chemistry (2 volumes). I currently serve on the Editorial Boards of *Crystal Growth & Design*, *Chemical Communications*, the *Journal of Coordination Chemistry*, and *Supramolecular Chemistry*. I have published more than 660 articles in refereed journals.

4. I have authored thirteen patents. I have taught more than 10,000 students in undergraduate University chemistry courses and I have taught and supervised graduate students (at both the Masters and Ph.D. level) with a primary emphasis on materials testing, organic synthesis, X-ray crystallography, and crystallization. I am an expert in the fields of materials testing, crystal growth, crystal engineering, X-ray crystallography, organic chemistry, and

polymer chemistry. I have consulted widely for industry, particularly in the fields of pharmaceutical chemistry and polymer chemistry. A copy of my curriculum vitae is provided as Exhibit “A”.

Scope of Review

5. I have reviewed U.S. Patent No. 5,714,504 (“the ‘504 patent”) and U.S. Patent No. 5,877,192 (“the ‘192 patent”). I have reviewed the prosecution histories for these patents. I have also reviewed relevant portions of the Court’s prior claim construction decision in *AZ v. DRL*, as discussed below. I have reviewed a portion of a Declaration of Wayne Genck, Ph.D. in this case, dated October 7, 2011, as discussed below. I have reviewed portions of the Joint Claim Construction and Prehearing Statement filed in this case. I have also reviewed a few other specific items mentioned in my comments below.

6. I have been asked to provide comments on the meaning to a person of ordinary skill in the art of certain claim terms of the ‘504 and ‘192 patents, pertaining to salt scope and optical purity issues, and have provided those comments below. I have not considered any claim construction issues other than those discussed below, and have not been asked to consider any other issues in this case.

Credentials of One of Ordinary Skill in the Art

7. I have reviewed paragraph 32 of Dr. Genck’s Declaration mentioned above, in which he stated:

32. I have reviewed U.S. Patent No. 5,714,504 (“the ‘504 Patent” (D.I. 86-2)) which is based on U.S. Patent Application No. 376,512 filed January 23, 1995 (“the ‘512 application”), which references two prior applications filed in 1994 and 1993. I have also reviewed the Patent Office prosecution history of the ‘504 patent. It is my opinion that, at the time of these filings in the 1993-1995 time frame, one of ordinary skill in the art to which the patent pertains would have a Ph.D. in Chemistry, Chemical Engineering, Pharmaceutical Sciences or Pharmaceutical Engineering, or a B.S. and 2 – 5 years of experience with organic

synthesis, separation, purification, and crystallization techniques in the pharmaceutical industry. This experience should also include testing and analytical techniques such as differential scanning calorimetry, thermogravimetric analysis and X-ray powder diffraction analysis.

8. Based on my background, education and experience over the past 40+ years, I am able to comment on the knowledge of such a person at the relevant time. In short, Dr. Genck's view is reasonable, and I agree with it. I would also apply it to the '192 patent, which was filed April 11, 1997 and is related to the '504 patent. The qualifications and skill set of a person of ordinary skill in the art in 1993, 1995 or 1997 would have been the same.

Issues Regarding "Salt" Scope In Both Patents

"alkaline salt" -- '504 patent

9. Each of claims 1, 6 and 7 of the '504 patent calls for an "alkaline salt" of (-)-omeprazole. I am informed that Hanmi submits that this term should be construed as follows:

"Na⁺, Mg²⁺, Li⁺, K⁺, Ca²⁺ or N⁺(R)₄ salt"

I agree that a person of ordinary skill in the art reading the '504 patent's application as filed on January 23, 1995 (Application No. 376,512) would interpret "alkaline salt" as Hanmi has proposed. A number of reasons support this conclusion.

10. The term "alkaline salt" is not defined in independent claims 1, 6 or 7. However, the specification is clear as to its meaning and expressly defines the term as the Na⁺, Mg²⁺, Li⁺, K⁺, Ca²⁺ or N⁺(R)₄ salts. The '504 patent specification clearly and consistently states that the compounds of the invention are the five inorganic salts and one organic genus of salts of an enantiomer of omeprazole. First, the Abstract on the cover page of the patent states that "[t]he novel optically pure compounds Na⁺, Mg²⁺, Li⁺, K⁺, Ca²⁺ or N⁺(R)₄ salts of [the enantiomers of omeprazole]" as well as processes for the making and using them, as well as intermediates, are the subject matter of the '504 patent. This statement limits the patent right out of the box.

11. Next, the “Detailed Description of the Invention” portion of the specification expressly defines salt scope as follows:

The present invention refers to the new Na^+ , Mg^{2+} , Li^+ , K^+ , Ca^{2+} and $\text{N}^+(\text{R})_4$ salts of the single enantiomers of omeprazole, where R is an alkyl with 1-4 carbon atoms, i.e. Na^+ , Mg^{2+} , Li^+ , K^+ , Ca^{2+} and $\text{N}^+(\text{R})_4$ salts of (+)-5-methoxy-2-[[(4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H- benzimidazole and (-)-5-methoxy-2-[[(4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H- benzimidazole, where R is an alkyl with 1-4 carbon atoms.”

Col. 2, lines 42-49 (emphasis added). A person of ordinary skill in the art would take these statements at face value, and conclude that no other salt forms were contemplated at the time of filing. Clearly, in my judgment, because AstraZeneca defined the six named salt species as *the present invention*, and not simply examples of permissible salt species, the claim would be understood to match this express definition.

12. The specification further identifies the Na^+ , Ca^{2+} and Mg^{2+} salts as “[p]articularly preferred” salts, and the Na^+ and Mg^{2+} salts of omeprazole (according to compounds Ia and Ib) as the “[m]ost preferred salts according to the invention.” (col. 2, line 50 – col. 3, line 15).

Beyond the most preferred Na^+ and Mg^{2+} salts, the ‘504 patent states that the alkaline salts are limited to the six species disclosed: “alkaline salts of the single enantiomers of the invention are, as mentioned above, beside the sodium salts (compounds Ia and Ib) and the magnesium salts (compounds IIa and IIb) exemplified by their salts with Li^+ , K^+ , Ca^{2+} and $\text{N}^+(\text{R})_4$, where R is an alkyl with 1-4 C-atoms.” (col. 5, lines 7-11). Because none of these other salts (Li^+ , K^+ , Ca^{2+} and $\text{N}^+(\text{R})_4$) were actually “exemplified” in the sense of having been prepared and disclosed, the ‘504 patent clearly defined alkaline salts as the six species -- two that were made (see Examples 1-7) and four that were not. In light of the way the ‘504 patent specification was drafted, one of ordinary skill in the art would clearly understand that the term “alkaline salt” of claims 1, 6 and 7 of the ‘504 patent would be limited to the Na^+ , Mg^{2+} , Li^+ , K^+ , Ca^{2+} and $\text{N}^+(\text{R})_4$

salt species. No hint of any broader disclosure would have been recognized by the skilled artisan.

13. The prosecution history of the '504 patent confirms that the construction of "alkaline salt" is limited to the Na^+ , Mg^{2+} , Li^+ , K^+ , Ca^{2+} or $\text{N}^+(\text{R})_4$ salts. According to the cover page of the '504 patent, the '504 patent was filed as Application No. 376,512 ("the '512 application") on January 23, 1995 as a continuation-in-part of Ser. No. 08/256,174. There were 34 claims in the '512 application as originally filed. ('512 application, pp. 26-32.) Consistent with the scope of the original specification filed on January 23, 1995, most of the original claims of the '512 application were directed to the six particular salt compounds of omeprazole's enantiomers. (Claims to a heterocyclic intermediate and processes of preparing particular compounds were also present, but I do not consider them relevant to my analysis.) Original claim 1 of the '512 application is representative:

1. An optically pure enantiomeric compound comprising a Na^+ , Mg^{2+} , Li^+ , K^+ , Ca^{2+} or $\text{N}^+(\text{R})_4$ salt of (+)-5-methoxy-2-[[(4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H- benzimidazole or (-)-5-methoxy-2-[[(4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H- benzimidazole, wherein R is an alkyl with 1-4 carbon atoms.

'512 application, p. 26. None of claims 1-34 of the '512 application as originally filed generically claimed an "alkaline salt" of (-)-omeprazole; instead, all original claims on the enantiomeric compounds were directed to only these six salt species, or a subset of them (e.g., claim 30). '512 application at pages 26-32. This further supports my conclusions that the skilled artisan would not give broad play to the claim term "alkaline salt."

14. On August 12, 1996, claim 1 and other original enantiomer claims were rejected based on prior art and for obviousness-type double patenting (based on the parent application, No. 256,174, which was pending at that time). August 12, 1996 Office Action. In a January 21, 1997 Examiner interview summary record, the Examiner suggested that not all alkaline salt

forms of (-)-omeprazole would be encompassed within the scope of the claims, stating: “A pharmaceutical formulation for oral administration of pure solid state (-) enantiomer of omeprazole Na-salt may be allowable *after reviewing the data in affidavit form. . . . The scope of the claim will depend on the data submitted.*” (emphasis added).

15. In a February 12, 1997 Amendment, AstraZeneca cancelled all of original claims 1-34 and added new claims 35-44, which later issued as claims 1-10 of the '504 patent. These new claims introduced the term “alkaline salt” for the first time, in contrast to the original claims discussed above which were limited to the six salts. February 12, 1997 Amendment. When it presented the new claim set in that Amendment, AstraZeneca did not point out where in the specification support existed to claim a broader genus of alkaline salts as opposed to the six salts defined in the specification as “the present invention.” As I have pointed out above, the specification does not describe any broader genus of “alkaline salts,” but only describes the six salt species.

16. When it filed the February 12, 1997 Amendment, AstraZeneca also submitted a Declaration of Dr. Andersson. The Andersson Declaration reported on two clinical studies involving both the sodium salt and the magnesium salt of (-)-omeprazole. Based on the clinical studies reported in the Andersson Declaration, AstraZeneca argued that the sodium and magnesium salts of (-)-omeprazole unexpectedly exhibited a different and more advantageous pharmacokinetic profile than racemic omeprazole. These results were specifically attributed to the sodium and magnesium salts used in the clinical studies. The Examiner then allowed the pending claims on April 25, 1997.

17. From the prosecution history, it is clear that AstraZeneca never made any arguments rebutting the Examiner’s statement in the interview summary that “[t]he scope of the claim will

depend on the data submitted.” Thus, the prosecution history as a whole confirms a claim scope that is no broader than the named species (based on “*the data submitted*” by the applicants), and is consistent with a straightforward reading of the ‘512 application as originally filed, which included not only a precise definition of salt scope, but also no hint that other salts were contemplated at the time of filing in 1995.

18. I am aware of the fact that the new claim set presented during prosecution included dependent claims, now issued as claims 3 and 10 of the ‘504 patent, which were directed to the six salt species discussed above. I am also generally familiar with the doctrine of claim differentiation, as meaning that independent claims are usually broader in scope than the dependent claims. However, I am informed that, legally, claim differentiation is a rebuttable presumption. Here, I have no trouble concluding that the ‘512 application as filed in January 1995 would “trump” the new claim set added later during prosecution. I note again in this regard that when it filed its replacement claim set, AstraZeneca never pointed out to the Patent Office precisely where in the ‘512 specification a concept of “alkaline salt” broader than the express definition of six salt species is disclosed. As I stated above, a person of ordinary skill in the art in the mid-1990’s would find no basis in the as-filed ‘512 application for any concept broader than the six salt species originally disclosed, which were expressly defined as “the present invention”.

19. AstraZeneca’s proposed construction of alkaline salt as a “basic salt (here, a salt in which (-)-omeprazole is negatively charged) that is suitable for use in a pharmaceutical formulation” is unsupported. First, “suitable for use in a pharmaceutical formulation” does not relate to the scope of the salts. Neither the specification nor the prosecution history hints at such a definition.

20. Second, there is no support in the specification or prosecution history for “alkaline salt” being defined as any “basic salt.” The ‘512 patent application refers to six particular salt forms, and no others.

“pharmaceutically acceptable salt” – ‘192 patent

21. Independent claims 1, 2 and 12 call for (-)-omeprazole or a “pharmaceutically acceptable salt” thereof. I am informed that Hanmi submitted two claim constructions as follows:

“Main” Construction based on “incorporated” ‘512 Spec’n: “ Na^+ , Mg^{2+} , Li^+ , K^+ , Ca^{2+} or $\text{N}^+(\text{R})_4$ salt”,

“Alternative” Construction based on ‘192 Spec’n: “an acid or alkaline pharmaceutically acceptable non-toxic salt.”

Joint Claim Construction Statement, Appendix D.

22. “Pharmaceutically acceptable salt” is not *per se* defined in the ‘192 patent claims. The ‘192 patent specification, however, first refers to the parent ‘512 application’s disclosure of the salt forms of (-)-omeprazole: “[t]he description of the salt forms of the single enantiomers of omeprazole and the process of making the same is herein incorporated by reference to copending Ser. No. 08/376,512.” (‘192 patent, col. 1, lines 10-13 -- I note that the ‘512 application issued as the ‘504 patent). While I am informed there may be a legal issue as to whether this was a sufficient “incorporation by reference” of the entire prior application or specific portions of it, in the following comments I have been asked to assume that the entire ‘512 application was incorporated by reference into the ‘192 patent.

23. Based on that assumption, an unusual situation is presented because the ‘192 patent would contain two distinct definitions of suitable salt scope. On the one hand, the particular “salt forms” of the ‘512 application, if incorporated into the ‘192 patent, would be understood to

be limited to the expressly described salt species (*e.g.*, Na^+ , Mg^{2+} , Li^+ , K^+ , Ca^{2+} and $\text{N}^+(\text{R})_4$), for the reasons I have provided above.

24. On the other hand, despite the incorporation by reference of the parent '512 application (which is restricted to six particular salts), the '192 specification went on to include an explicit definition of "pharmaceutically acceptable salt."

The term "pharmaceutically acceptable salt" refers to both acid and alkaline pharmaceutically acceptable non-toxic salts.

'192 patent, col. 4, lines 13-16. Thus, based on this explicit definition, one of ordinary skill in the art would understand the term should be construed as meaning "an acid or alkaline pharmaceutically acceptable non-toxic salt" in the '192 independent claims. Because AstraZeneca expressly defined "pharmaceutically acceptable salt" as "an acid or alkaline pharmaceutically acceptable non-toxic salt" in the '192 specification, in my view that definition would be considered dominant and controlling by a person of ordinary skill in the art.

25. Thus, while the '192 patent's specification (with reference to the parent '504 patent) is confusing, in my judgment the broader definition of "an acid or alkaline pharmaceutically acceptable non-toxic salt" in the '192 patent at col. 4, lines 13-16 cannot be ignored. Although I have never seen this type of situation, one of ordinary skill in the art would at least attempt to reconcile the apparent contradiction in the incorporated '512 application's salt scope ("***The present invention refers to the new Na^+ , Mg^{2+} , Li^+ , K^+ , Ca^{2+} and $\text{N}^+(\text{R})_4$ salts of the single enantiomers of omeprazole...***") with the '192 patent's broader definition ("***an acid or alkaline pharmaceutically acceptable non-toxic salt***"), by combining them. On the assumption that the entire parent '512 application's disclosure is incorporated by reference into the '192 patent, that disclosure pertains solely to the six species of alkaline salts, as discussed above. The "pharmaceutically acceptable salts" as defined in the '192 patent include both acid and alkaline

salts, and so the incorporated disclosure would be understood to pertain only to alkaline pharmaceutically acceptable salts, and not acidic species. Under a “combined” construction, the acid component would be broadly defined and the alkaline component would be restricted per the ‘504 patent’s definition. In my view, such a “combined” approach would be the only rational solution from the standpoint of one of ordinary skill in the art.

26. My views that the acid component should not be ignored are supported by the Court’s statements in *AZ v. DRL*, where AstraZeneca previously asserted that “pharmaceutically acceptable salt” in the ‘192 claims encompassed both acid and alkaline species. The Court’s decision states:

13. “pharmaceutically acceptable salt

This term appears in claims 1, 2, 7–9 and 12. Astra contends that this term should be construed to mean “both acid and alkaline nontoxic ionic compound.” DRL contends that this term need not be construed and the ordinary meaning as understood by those of ordinary skill in the art should apply. However, if construction is required, DRL proposes that the phrase be construed as “a salt that is suitable for use in a pharmaceutical formulation.”

Once again, Astra’s basis for its proposed construction of this term is nowhere addressed in Astra’s claim construction papers. The Court, therefore, accepts DRL’s argument that this term need not be construed.

Page *62. Although it is unclear why AstraZeneca could not point the Court to the specific definition at column 4, lines 13-16 of the ‘192 patent, AstraZeneca clearly urged a position then that is contradictory to what I am informed is its position here -- the “acid” part of the definition can simply be ignored.

Issues Regarding Optical Purity In Both Patents

“(–)-enantiomer of 5-methoxy-2[[[4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benzimidazole” – ‘504 patent independent claims 1, 6 and 7 and “optically pure” – dependent claim 2

27. Each of independent claims 1, 6 and 7 of the '504 patent expressly recites a salt of the “(-)-enantiomer of 5-methoxy-2[[(4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benzimidazole.” I am informed that Hanmi asserts that the quoted term should be construed as follows:

“(-)-omeprazole” or the “(-)-enantiomer of omeprazole” [“(-)-omeprazole” is also known as “(S)-omeprazole”].

I agree that a person of ordinary skill in the art reading the '504 patent's application as filed on January 23, 1995 would interpret this claim term as Hanmi has proposed. Again, a number of reasons support this conclusion. Below, I address what I understand to be AstraZeneca's contentions seeking to have specific, numerical optical purity limitations included as part of the construction. I also address here the claim term “optically pure” in claim 2 of the '504 patent because they are intertwined.

28. In *AZ v. DRL*, the Court noted that:

The claims at issue expressly require the alkaline salts of the (-)-enantiomer of omeprazole. '504 patent, col. 14, lines 6-10. By focusing a person skilled in the art on the enantiomer, Astra asserts that the claims obviously require some level of optical purity. Indeed, a person of ordinary skill in the art would know that “[t]he ‘(-)’ denotes that the compound has some level of optical purity.”

Pages *18-19. The Court's recognition of the well known ‘(-)’ symbol in the compound's name, as denoting one of the enantiomers as opposed to the racemate or the other enantiomer, is consistent with Hanmi's proposed construction – “(-)-omeprazole or the (-)-enantiomer of omeprazole.”

29. The Court went on to construe compounds of the '504 patent independent claims 1, 6 and 7 as having “high optical purity” of “at least 94% enantiomeric excess” (e.e.), basically agreeing with AstraZeneca's position (pages *19-21). The Court then considered the term “optically pure” in dependent claim 2, and also adopted AstraZeneca's position: “essentially

free of the (+)-enantiomer of omeprazole” and “at least 98% enantiomeric excess (e.e.)” (pages *21-23).

30. With due respect, the ‘504 patent’s specification and prosecution history do not support adding numerical limitations to any of the ‘504 claims (or the ‘192 claims, as discussed below), despite AstraZeneca’s apparent prior arguments which appeared to persuade the Court’s constructions.

31. The ‘504 patent expressly defines two levels of optical purity -- “optically pure” and “very high optical purity:”

With the expression “***optically pure*** Na⁺ salts of omeprazole” *is meant* the (+)-enantiomer of omeprazole Na-salt essentially free of the (-)-enantiomer of omeprazole Na-salt and the (-)-enantiomer essentially free of the (+)-enantiomer, respectively.

* * *

Because it is possible to purify optically impure or partially pure salts of the enantiomers of omeprazole by crystallization, they can be obtained in ***very high optical purity, namely*** $\geq 99.8\%$ enantiomeric excess (e.e.) even from an optically contaminated preparation.

Col. 3, lines 31-36 and 43-48 (emphasis added). The ‘504 specification makes clear that the term “optically pure” means “the (-)-enantiomer essentially free of the (+)-enantiomer.” Col. 3, lines 31-36 . It also makes clear that “very high optical purity” means $\geq 99.8\%$ e.e.” Col. 3, lines 43-48. AstraZeneca chose to limit the highest level of optical purity numerically and, while the ‘504 specification *disclosed* certain Examples as preferred embodiments, no *claim* of the ‘504 patent recites or requires “very high optical purity.”

32. On the other hand, AstraZeneca could have, but did not, limit the definition of “optically pure” in the ‘504 claims numerically. (I refer to AstraZeneca’s U.S. Patent 6,875,872, which has the same specification as the ‘504 patent.) Instead, the ‘504 patent’s express definition at col. 3, lines 31-36 avoided any numerical lower limit. Thus, the working

Examples in the ‘504 patent had to have formed the basis for AstraZeneca’s prior arguments calling for a definition with a numerical limitation. But read in context, the Examples beginning in column 6 are merely illustrative -- as the term “Example” itself means -- and I see no basis for including any e.e. % reported as a lower limit of optical purity in the Examples in the claims. In fact, the ‘504 specification prefaces the Examples with the following unambiguous statement:

The invention is *illustrated* by the following *examples* using *preferred procedures* for the preparation of optically pure sodium salts and magnesium salts.

‘504 patent, col. 6, lines 26-28 (emphasis added). While Examples of 98% e.e. are reported, a conclusion that “optically pure” in claim 2 *requires* a minimum of 98% e.e. would be contrary to the express definition in the specification (“essentially free of” at col. 3, lines 31-36), as well as the suggestion at col. 6, lines 26-28 that “non-preferred” procedures could yield lower optical purity values, and still be within the scope of the claims.

33. Accordingly, one of ordinary skill in the art would understand that the term “optically pure” in claim 2 would be given its express definition in column 3 -- “the (-)-enantiomer essentially free of the (+)-enantiomer” (‘504 patent at col. 3, lines 31-36). I see no basis in the patent or prosecution history for limiting claim 2 to 98% e.e., as that would be based on preferred embodiments of the Examples.

34. If dependent claim 2 is not limited numerically, clearly no basis exists for AstraZeneca to have urged in the prior *AZ v. DRL* case, or now, that independent claims 1, 6 and 7 of the ‘504 patent should require any specific lower limit of optical purity. Yet, in *AZ v. DRL*, the Court accepted AstraZeneca’s position that Example 12 provides a basis for a minimum optical purity of 94% e.e. However, a skilled artisan would recognize that the working Examples cannot limit claim scope for the reasons set forth above. Moreover, even if

they could, Example 12 provides no support for the subject matter of claims 1, 6 and 7. Those claims are directed to alkaline *salts* of (-)-omeprazole, whereas Example 12 forms the free base or neutral (*i.e.*, non-salt) form of (-)-omeprazole. Indeed, Example 12 illustrates the final stage of what is characterized as a novel *process* of making the enantiomers. The ‘504 patent states that “The present invention in a further aspect provides a novel method for preparing the novel compounds of the invention in large scale. This novel method can also be used in large scale to obtain single enantiomers of omeprazole in neutral form.” ‘504 patent, col. 2, lines 11-15. It appears that the process is claimed in AstraZeneca’s U.S. Patent 5,693,818, which issued from the ‘504 patent’s parent application 256,174. Clearly, in a general sense, the enantiomers of omeprazole in non-salt or neutral form are not part of the invention of the ‘504 patent, because they were admittedly known in the prior art. The ‘504 patent additionally states that “The separation of the enantiomers of omeprazole in analytical scale is described in e.g. *J. Chromatography*, 532, 305-19 (1990), and in a preparative scale in DE 4035455.” ‘504 patent, col. 1, lines 27-29. Thus, Example 12 is not related to the subject matter of claims 1, 6 and 7 of the ‘504 patent, which are directed to salts.

35. Here, nothing in the specification of the ‘504 patent declares or signifies to a person of ordinary skill in the art that any salt compound must have a minimum of 94% e.e. In fact, that value is merely the reported result for one example – an example of a free base, non-salt compound not related to the subject matter of claims 1, 6 and 7 of the ‘504 patent. A person of ordinary skill in 1995 would have understood that nothing in Example 12 lays down a ground rule that all salt compounds in the patent have a minimum of 94% e.e.

36. In sum, the compound in claims 1, 6 and 7 is simply a salt of (-)-omeprazole, and claim 2 signifies a higher level of optical purity – essentially free of the (+)-enantiomer, based

on the express definition at 3:31-36. The only term defined as having a specific, numeric lower limit is “very high optical purity,” which is not claimed in the ‘504 patent.

37. The ‘504 patent’s prosecution history provides further support for Hanmi’s optical purity constructions. As discussed above, the ‘512 application as filed contained 34 claims. All of the relevant original claims called for “optically pure” enantiomers, and none recited a specific numerical lower limit of optical purity. Original claim 1 is again shown below:

1. An optically pure enantiomeric compound comprising a Na^+ , Mg^{2+} , Li^+ , K^+ , Ca^{2+} or $\text{N}^+(\text{R})_4$ salt of (+)-5-methoxy-2[[4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benzimidazole or (-)-5-methoxy-2[[4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benzimidazole, wherein R is an alkyl with 1-4 carbon atoms.

‘512 application at p. 26.

38. Following the August 12, 1996 rejection of claims, AstraZeneca responded February 12, 1997 by cancelling all then-pending claims (1-34) and adding new claims 35-44 (now issued as claims 1-10 of the ‘504 patent), as I discussed above. In the new claim set, the independent claims (corresponding to patent claims 1, 6 and 7) were broader than any original claim to the enantiomers in that they did not characterize the compounds as “optically pure.” The term “optically pure” only appeared in dependent claim 36, which became claim 2 of the ‘504 patent. Thus, while “optically pure” in claim 2 should be construed in accordance with the patent’s express definition at col. 3, lines 31-36, by dropping that term from the original independent claims, AstraZeneca signaled to a skilled artisan that claims other than claim 2 encompass some measure of optical impurity. Nothing in the remainder of the prosecution history supports AstraZeneca’s position that claims 1, 6 and 7 are limited to 94% e.e. and that claim 2 should be limited to 98% e.e.

“optically pure” – ‘504 patent claim 2

39. Claim 2 of the '504 patent recites an "optically pure" alkaline salt. I am informed that Hanmi submits that this term should be construed as follows:

"essentially free of (+)-omeprazole alkaline salt, *i.e.*, the single enantiomer".

I agree with this proposed construction, because the express definition of "optically pure" in the '504 patent's specification at col. 3, lines 31-36, should control for the reasons set forth above. The key aspect of the definition is "essentially free of," but without a numerical component.

"(-)-enantiomer of 5-methoxy-2[[4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benzimidazole" – '192 patent

40. Each of independent claims 1, 2 and 12 of the '192 patent expressly recites "the (-)-enantiomer of 5-methoxy-2[[4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benzimidazole." I am informed that Hanmi submits that this term should be construed the same as in the '504 patent as:

"(-)-omeprazole" or the "(-)-enantiomer of omeprazole."

I agree that a person of ordinary skill in the art would not include a numerical optical purity limitation of 98% e.e., for the following reasons.

41. In *AZ v. DRL*, the Court noted that in the context of the parent '504 patent, a person of ordinary skill in the art would know that "[t]he '(-)' denotes that the compound has some level of optical purity," citing certain cases. Pages *18-19. Again, the Court's recognition of the well known '(-)' symbol in the compound's name, as denoting one of the enantiomers as opposed to the racemate or the other enantiomer, is consistent with Hanmi's proposed construction – "(-)-omeprazole or the (-)-enantiomer of omeprazole."

42. The Court construed the phrase "consisting essentially of the (-)-enantiomer of 5-methoxy-2[[4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benzimidazole" of the '192 patent independent claims 1, 2 and 12 as "a (-)-enantiomer that is essentially free of its

(+) contaminant, which means at least 98% e.e.,” basically agreeing with AstraZeneca’s position (pages *29-31, quotation at *31). I respectfully disagree with this construction.

43. The ‘192 patent specification first discusses the term “(-)-enantiomer of [omeprazole]” at col. 1, lines 17-20, and goes on to define the term “single enantiomer” of (-)-omeprazole as “substantially free from its (+) enantiomeric contaminant.” Col. 1, lines 21-23. The claims of the ‘192 patent do not recite the term “single enantiomer.” Nonetheless, I would have no problem if the Court equates the terms and adds “substantially free from its (+) enantiomeric contaminant” to Hanmi’s proposed construction. In my view, however, the ‘192 claims would not be understood by a person of ordinary skill in the art to include the 98% e.e. limitation in the ‘192 claims, which I am informed AstraZeneca presses here without regard to the phrase “substantially free from its (+) enantiomeric contaminant” appearing at col. 1, lines 21-23.

44. From my perspective, one of ordinary skill in the art would find that no basis exists for AstraZeneca’s position that the claims should be limited to any specific lower limit of optical purity. The ‘192 patent’s specification only states that the expression “single enantiomer” refers to the fact that the (-)-enantiomer is substantially free from its (+) enantiomeric contaminant.” *See* ‘192 patent at col. 1, lines 16-23. Even if the Court equates the claimed “(-)-enantiomer” with the unclaimed term “single enantiomer” and construes the independent claims as “substantially free of”, there should be no inclusion of 98% e.e. as the floor in independent claims 1, 2 and 12.

45. First, there is no mention or discussion anywhere in the ‘192 patent’s specification as printed of 98% e.e., or any other numerical lower limit.

46. Second, as I noted above under the “salt” discussion, the ‘192 patent’s underlying application (Appl’n. No. 833,962) referenced the parent ‘512 application. As before, I have been asked to assume the full parent application’s disclosure was incorporated into the ‘192 patent. On that assumption, the ‘192 independent claims still should not be limited to 98% e.e. It is significant that while all of the original claims of the parent ‘512 application claim no more than six particular *salts* of (-)-omeprazole, the ‘192 patent discloses and claims use of the *free base or neutral form* of (-)-omeprazole, *or* a pharmaceutically acceptable salt thereof. ‘192 patent at col. 1, lines 16-22 and independent claims 1, 2 and 12. If the ‘192 claims are limited to 98% e.e., they would exclude the free base (-)-enantiomer reported in Example 12 of the ‘504 patent / ‘512 application, which states that the compound was obtained at 94% e.e. (‘504 patent, col. 10, line 48 to col. 11, line 3) – the only Example of making the free base (-)-enantiomer by the allegedly “novel process” that is reported.

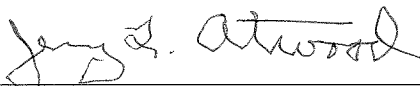
47. Moreover, the Court in the prior *AZ v. DRL* claim construction opinion agreed with AstraZeneca’s arguments that the phrase “consisting essentially of the (-)-enantiomer of (-)-omeprazole” in the independent claims of the ‘192 patent should be construed consistently with the term “optically pure” in claim 2 of the ‘504 patent. Pages *28-30. I cannot take issue with that approach, given the ‘504 patent’s definition of “optically pure” as “essentially free of the (+)-enantiomer” (col. 3, lines 31-36) vs. the ‘192 patent -- *if* the term “(-)-enantiomer” (as opposed to “single enantiomer”) is found to be defined as “substantially free from its (+)-enantiomeric contaminant” (col. 1, lines 16-23). Regardless, I have pointed out in detail above that limiting “optically pure” in claim 2 of the ‘504 patent to 98% e.e. is at odds with the express definition of “optically pure” not requiring a numerical limit, the presence of non-limiting “Examples,” and AstraZeneca’s actions in prosecution where it cancelled the initial

claims requiring “optically pure” compounds and replaced them with optically impure claims except for claim 2. For the same reasons, to the extent the ‘504 patent and its prosecution history are relevant, independent claims 1, 2 and 12 of the ‘192 patent should not be limited to 98% e.e. minimum because the basis of that finding was the ‘504 disclosure.

48. From my review, nothing in the prosecution history of the ‘192 patent requires a 98% e.e. limitation in the independent claims.

I declare under penalty of perjury that the foregoing is true and correct.

Dated: November 3, 2011



Jerry L. Atwood, Ph.D.

EXHIBIT A

CURRICULUM VITAE

Jerry L. Atwood

Personal

Date of Birth: July 27, 1942

Place of Birth: Springfield, Missouri

Education

B.S., Southwest Missouri State, Chemistry and Mathematics, 1964

Ph.D., University of Illinois, 1968

Professional Experience

Assistant Professor, University of Alabama, 1968-1972

Associate Professor, University of Alabama, 1972-1978

Professor, University of Alabama, 1978-1987

Visiting Professor, Imperial College, 1977

Visiting Professor, University of Sussex, 1985

University Research Professor, University of Alabama, 1987 - 1994

Professor and Chairman, University of Missouri-Columbia, 1994-

Curators' Professor, University of Missouri-Columbia, 1999-

Professional Activities

Co-Editor-in-Chief, *New Journal of Chemistry* (2005-)

Editor, *Journal of Supramolecular Chemistry* (2000-2004)

Editor, *Supramolecular Chemistry* (1992-2000)

Associate Editor, *Chemical Communications* (1996-2006)

Consulting Editor, *Journal of Chemical Crystallography* (1999-)

Editor, *Journal of Chemical Crystallography* (1985-1998)

Regional Editor, *Journal of Coordination Chemistry*, A & B (1985-1993)

Editor, *Journal of Inclusion Phenomena* (1983-1991)

Editorial Advisory Board, *Crystal Growth & Design* (2000-)

International Advisory Editorial Board, *New Journal of Chemistry* (2003-)

Editorial Board, *Supramolecular Chemistry* (2000-)

Editorial Board, *Journal of Coordination Chemistry* (1993-)

Editorial Board, *Journal of Organometallic Chemistry* (1986-2000)

Editorial Board, *Crystal Engineering* (1998-)

Co-Editor, *Inclusion Compounds* (five volumes)

Co-Editor, *Comprehensive Supramolecular Chemistry* (ten volumes)

Co-Editor, *Encyclopedia of Supramolecular Chemistry* (two volumes)

Member, American Chemical Society

Member, American Institute of Chemical Engineers

Member, Royal Society of Chemistry

Member, American Crystallographic Association

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Publications Summary

Publications in Refereed Journals 672

Patents 13

Honors and Awards:

1986	Burnum Award for Teaching and Research, U of Alabama
1987	University Research Professor, U of Alabama
1989	von Humboldt Senior Scientist Award, Germany
1992	Japanese Society for the Promotion of Science Award
1996	Outstanding Alumni Award, SMSU
1999	Curators' Professor, University of Missouri (MU)
2000	President's Award for Research and Creative Activity, MU
2000	Izatt-Christensen International Macrocyclic Chemistry Award
2000	Polish Academy of Science, Elected Foreign Member
2002	Alumni-Faculty Award, MU
2005	Royal Society of Chemistry, Elected Fellow
2005	Honorary Medal of the Institute of Physical Chemistry, Polish Academy of Sciences
2005	Midwest Chemist Award, American Chemical Society
2010	Distinguished Faculty Alumni Award, MU

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